

REMARKS

I. STATUS OF CLAIMS

Upon entry of the present amendment, claims 1-4, and 8-21 will be pending, and claims 5-7 will be canceled. Applicants note with appreciation the Examiner's indication that claims 1-3 are allowed.

II. SUPPORT FOR CLAIM CHANGES

Support for changes made in the Preliminary Amendment filed on February 2, 2001 has been explained therein.

Support for the amendment to claim 4 can be found, *inter alia*, in the specification at column 2, lines 23-27, column 4, lines 19-22, FIG. 3, and FIG. 4. If the supports can move relative to each other, and there is no affixation of the supports to the resilient body, then the supports must also be able to move relative to the resilient body. Moreover, FIG. 3 and FIG. 4 show that the supports are not affixed to the resilient body, and therefore are free to move relative to it, so that the prosthetic parts move naturally with the adjacent natural anatomy.

Support for the amendment to claim 8 can be found in the same places in the specification as support for the amendment to claim 4.

Claim 9 has been amended to remove reference to discectomy surgery, since the specification is not so limited. See column 2, line 61 to column 3, line 3. Reference to implantation "in the patient's spine" has been moved to make the claim more grammatically correct, and does not involve any new matter, being fully supported by the original claim and by column 3, line 3 of the specification. Finally, claim 9 has been amended to recite that the concaval-convex elements are capable of

movement relative to the resilient disc, which is supported as described above for similar language in claim 4.

Claims 16 and 19 have been rewritten in independent form by incorporating the limitations of claim 4 (prior to the present amendment).

Support for new claims 20 and 21 can be found in, e.g., FIG. 3 and FIG. 10.

No new matter has been added.

III. WRITTEN ASSENT OF ASSIGNEE

At page 2 of the Office action, the Examiner has objected to this application under 37 C.F.R. § 1.172(a) as lacking written consent of all assignees owning an undivided interest in the patent.

Applicants note that an Assent of Assignee and Offer to Surrender were filed, along with an assignment from inventors Bryan and Kunzler, on February 2, 2001, with the reissue application filing. Nevertheless, Applicants include herewith an additional Consent of Assignee, together with a Statement under 37 C.F.R. § 3.73(b), in order to resolve any objection to the originally filed papers.

With respect to the amendments to the claims made above, Applicants note the provisions of MPEP § 1444, which provides:

During the prosecution of a reissue application, amendments are often made and additional errors in the patent are corrected. A supplemental oath/declaration need not be submitted with each amendment and additional correction. Rather, it is suggested that the reissue applicant wait until the case is in condition for allowance, and then submit a cumulative supplemental reissue oath/declaration pursuant to 37 C.F.R. 1.175(b)(1).

While Applicants believe that the present amendment places this application into condition for immediate allowance, the respectfully request deferral of the

requirement for submission of a supplemental reissue declaration until allowability has been indicated by the Examiner.

IV. ANTICIPATION REJECTION OVER MICHELSON

At pages 2-3 of the Office action, the Examiner has rejected claim 8 as anticipated under 35 U.S.C. § 102(b) by Michelson (U.S. Patent No. 5,015,247).

Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Michelson is directed to methods for introducing a threaded cylindrical spinal implant to promote bone fusion across the intervertebral space following excision of a damaged intervertebral disk. See column 6, lines 6-9. The implant is designed to “stabilize the adjacent spinal segments” in order to expedite the spinal fusion. See column 6, lines 23-26. Put another way, the method of Michelson is designed to implant a device that holds the vertebral bodies adjacent the damaged disk space in place relative to each other, and space them apart appropriately so that fusion of the two adjacent vertebral bodies can occur. In fact, the implant of Michelson is designed to enclose a bone graft, which can fuse with the adjacent vertebral bodies through openings in the curved cylindrical surface of the implant. See column 7, lines 1-4 and column 10, lines 3-14.

In fact, Michelson goes to some pains to make clear the distinction between his device and devices that allow movement. After summarizing several prior art patents relating to prosthetic or artificial discs for preserving spinal motion, Michelson says:

In summary then, these devices resemble the present invention only in that they are placed within the intervertebral space following the removal of a damaged disc. In that they seek to preserve spinal motion, they are diametrically different from the present invention which seeks to permanently eliminate all motion at that spinal segment.

See Michelson at column 1, lines 58-64.

By contrast, claim 8 recites implantation of an articulating prosthesis wherein the outer surfaces, which mate precisely with the milled bone surfaces of the vertebral bodies, are capable of motion relative to each other. The implant of claim 8 is designed to preserve spinal motion after implantation. Michelson's implant has a single outer surface, and so logically cannot move in this way. Because Michelson's method of implanting such an implant does not include each element of claim 8, there is no anticipation under 35 U.S.C. § 102(b), and the Examiner's rejection should be withdrawn.

V. OBVIOUSNESS REJECTION OVER MICHELSON AND SHEPPERD

At pages 3-4 of the Office action, the Examiner has rejected claims 4 and 9-15 under 35 U.S.C. § 103(a) as obvious over Michelson in view of Shepperd (U.S. Patent No. 4,863,476). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

The disclosure of Michelson, and some of its deficiencies with respect to the claimed invention, has been discussed above. Shepperd discloses a spinal implant that is expanded after insertion by rotation of a threaded rod, which interfaces with two cams. The movement of the cams expands the implant so that the outer surfaces contact the vertebral bodies and maintain the correct spacing between them. However, Shepperd does not teach or suggest milling the bone surfaces so that their

shape mates with the shape of the outer surfaces of the implant. While the Examiner has attempted to combine the teachings of Shepperd with those of Michelson, this attempted combination does not cure the deficiencies of either reference.

In one embodiment of Shepperd, the cams are moved outwardly, to provide a stable, immobile implant. *See FIG. 4 and column 3, line 56 to column 4, line 8.* In this case, combination with the teachings of Michelson fails to satisfy the requirement of claims 4 and 9 that the supports are capable of movement relative to the resilient body when implanted into the disc space. Once implantation of the Shepperd device is complete (i.e., portions 5 and 6 have been expanded by the cams), portions 5 and 6 are no longer capable of movement relative to the cams. The disclosure of Shepperd fails to cure the deficiencies of the disclosure of Michelson (described above) in this regard.

In another embodiment of Shepperd, the cams are moved inwardly, allowing portions 5 and 6 to move with the motion shown in FIG. 5. However, such a motion does not maintain the stability of the adjacent spinal segments relative to each other sufficiently that spinal fusion can occur, as required by the disclosure of Michelson. As a result, modifying the disclosure of Michelson to include this embodiment of Shepperd would destroy the function of Michelson.

Michelson makes clear that his device is intended to lock the position of the vertebral bodies relative to one another, and thereby facilitate the fusion of the vertebrae. As described in the Michelson patent:

The present invention relates to an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc.

The purpose of the present invention is to provide an implant to be placed within the intervertebral disc space and provide for the permanent elimination of all motion at that location. To do so, the device is space occupying within the disc space, rigid, self-stabilizing to resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebral to vertebra bony fusion' so as to assure the permanency of the result.

See Michelson at , column 1, lines 8-16.

In addition, Michelson distinguishes over the prior art (Bagby U.S. Patent 4,501,269) by emphasizing that his device does not allow for rocking of the vertebral bodies over the surface of the implant. Michelson states:

6. Spinal stability--The present invention is not only self-stabilizing, it also provides stability to the adjacent vertebra in at least three way [sic] that the BAGBY device cannot. First, the BAGBY device is placed transversely across the joint in the center, leaving both vertebra free to rock back and forth over this round barrel shaped axis, much like a board over a barrel, being used for a seesaw.

Secondly, as the BAGBY device lacks any specific design features to resist sliding, it may actually behave as a third body allowing the translation of the vertebra relative to the device and to each other.

See Michelson at column 4, lines 45-55.

As shown in FIG. 4, more than one implant is inserted into the disc space, thereby preventing the rocking motion that would result in the difficulties referred to above in the discussion of the Bagby patent.

Id., at column 10, lines 53-56.

One of ordinary skill in the art would not have modified the Michelson disclosure to incorporate the "rocking" embodiment of Shepperd in light of the clear teaching away from doing so contained in Michelson, and in light of the effective destruction of the

invention of Michelson that would occur. As a result, this worker would not have combined the references as suggested by the Examiner.

Irrespective of which embodiment of Shepperd one chooses to examine, the Examiner has failed to establish a *prima facie* case of obviousness of claim 4 or claim 9 thereover. Accordingly, the Examiner's rejection should be withdrawn.

VI. OBVIOUSNESS REJECTION OVER MICHELSON, SHEPPERD, AND FUHRMANN ET AL.

At page 4 of the Office action, the Examiner has rejected claims 16-19 under 35 U.S.C. § 103(a) as obvious over Michelson and Shepperd, as applied to claim 4, and further in view of Fuhrmann et al. (U.S. Patent No. 5,002,576). Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Apparently recognizing the failure of both Michelson and Sheppard to disclose the fluid-tight seal member of claim 16, the Examiner turns to Fuhrmann et al. as allegedly supplying the missing teaching. However, in addition to the deficiencies of Michelson and Sheppard as references (described in more detail above), there is no teaching or motivation in Michelson, Sheppard, or Fuhrmann et al. to introduce a fluid-tight seal member into either Michelson or Sheppard.

Fuhrmann et al. is directed to an endoprosthesis filled with a viscoelastic material. The viscoelastic material is disposed within a corrugated tube, capped by screwed-on or welded endplates, which tube keeps the viscoelastic material separate

from body fluids, and prevents excessive bulging (and preventing the cross-section of the implant from varying substantially). See column 1, lines 46-56.

However, in light of the geometry of the Michelson device, there does not appear to be any rational way to add a fluid seal member "around" the cylindrical device of Michelson without destroying an essential feature of the Michelson device. Michelson relies on both the bony ingrowth that occurs both from the vertebral bodies growing into the Michelson device, and on the bone graft disposed within the device growing out. Both of these occur through openings in the device, which openings would be closed if a fluid seal member were disposed around the cylindrical device of Michelson.

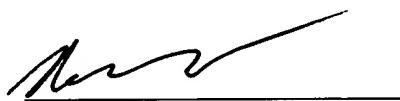
Similarly, there does not appear to be any motivation to combine such a fluid seal member with the teachings of Shepperd. To the contrary, such a seal would make it impossible to install the Shepperd device in the manner disclosed in Shepperd, because the seal would have to be pierced by the device that actuates the screw that drives the cams. See, e.g., FIG. 6 and FIG. 8 of Shepperd.

As described above, there is no motivation for one of ordinary skill in this art to have combined Michelson with Shepperd in the first place. In the present rejection, the Examiner has not only failed to supply this missing motivation, but has added an additional reference without the requisite motivation to combine its teachings with those of either Michelson or Shepperd. For at least these reasons, the Examiner has failed to establish a *prima facie* case of obviousness, and the rejection should be withdrawn.

Applicants respectfully submit that the claims define novel and nonobvious subject matter. An early notice of allowance is respectfully requested. If the Examiner believes that any issues remain to be resolved, he is respectfully requested to contact the undersigned at 404.815.6218 to schedule an interview to resolve these issues prior to issuance of a final Office action.

The Commissioner is hereby authorized to charge any deficiencies or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,



Bruce D. Gray
Reg. No. 35, 799

KILPATRICK STOCKTON LLP
Suite 2800, 1100 Peachtree Street
Atlanta, Georgia 30309-4530
(404) 815-6218